IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 8 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF DR. OZ HARMANLI

Defense expert Dr. Oz Harmanli is an ob-gyn with decades of experience. He has been board-certified in Obstetrics and Gynecology since 1997 and in Female Pelvic Medicine and Reconstructive Surgery since 2013. He estimates that he has performed thousands of midurethral sling procedures in the last 20 years. *See* Expert Report of Oz Harmanli, M.D. on TVT/TVT-O Midurethral Slings ("Harmanli Report"), p. 4 [Dkt. 6892-2]. Presently, he is the Chief of Urogynecology and Reconstructive Surgery and a Professor of Obstetrics and Gynecology at the Yale University School of Medicine. *Id.* at 1.

Plaintiffs have moved to exclude five categories of opinions from Dr. Harmanli for Wave 8: (1) opinions about the adequacy of Ethicon's warnings; (2) opinions about whether the mesh products are defectively or reasonably designed; (3) opinions about the clinical differences between mechanically cut and laser cut TVT mesh; and (4) opinions about the safety or efficacy of mesh products observed in his own practice; and (5) opinions about the degradation of

polypropylene or its clinical significance. [Dkt. 6895, pp. 1-2]. Plaintiffs' motion should be denied in its entirety, as explained below.

ARGUMENT

I. Dr. Harmanli's opinions regarding the adequacy of Ethicon's product warnings are reliable and admissible.

Most of Plaintiffs' challenge to Dr. Harmanli's warning opinions is devoted to argument about Dr. Harmanli's alleged lack of experience or expertise in FDA regulations or standards. Dr. Harmanli is a urogynecologist at Yale with decades of experience performing pelvic floor surgeries, counseling patients, teaching residents and fellows, and consulting with industry. Further, Dr. Harmanli testified that he has experience in drafting an IFU for a pessary device. *See* Harmanli Dep. at 61:5-8 [Dkt. 6892-3, p. 17]. Dr. Harmanli testified that he educated himself about the federal regulations and requirements for labeling throughout the years and in connection with his work drafting an IFU for the pessary device. This Court found Dr. Rosenzweig to be qualified to offer opinions on the sufficiency of product warnings based on similar experience in working on the IFU for an amnioinfusion catheter. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 (S.D. W. Va. 2014).

Nevertheless, Defendants agree that Dr. Harmanli will not offer opinions regarding FDA requirements or regulations, or Ethicon's compliance with them. However, Dr. Harmanli's underlying opinion that the risks of the TVT and TVT-O were (1) well known to physicians, and/or (2) included in the IFU is relevant, reliable, and admissible.

According to the FDA regulations governing warnings, a product IFU need not warn of risks that are known generally to the users of products. The FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are **commonly known to practitioners licensed by law to use the device**.

21 C.F.R. §801.10(c) (emphasis added); *see also Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). That makes sense, for otherwise product warnings would be so voluminous as to defy any worth.

Because of this legal standard, Ethicon is entitled to defend the adequacy and contents of its warnings by referencing what licensed surgeons would know about the risks associated with pelvic floor surgery, including surgery using mesh augmentation. That necessarily includes information that a surgeon would learn through education, clinical training and professional development. Since Ethicon's warnings are not to be judged by just what one particular surgeon knew, but by what commonly would be known to such physicians generally, Ethicon's experts can reference the common knowledge of surgeons in offering opinions concerning Ethicon's warnings. *Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff'd*, 162 F. App'x 231 (4th Cir. 2006) ("expert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by competent experts."); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (testimony regarding common knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant).

Plaintiffs' only other criticism of Dr. Harmanli's opinion that the risks of TVT and TVT-O were well known is that he "has never done any kind of survey or used any kind of formal methodology to determine what physician did or did not know with regard to pelvic mesh devices." [Dkt. 6895, p. 7]. As an example, Plaintiffs state Dr. Harmanli could not "state what

percentage of physician knew that chronic pain could result specifically from the TVT mesh at the time of launch." *Id.*

Ironically, Defendants have moved to exclude the testimony of Plaintiffs' regulatory expert Peggy Pence, Ph.D. because she has employed no methodology—such as a survey—to determine what physicians know, and Plaintiffs have been dismissive that argument. *See* Pls.' Opp. to Defs.' Motion to Exclude Peggy Pence [Dkt. 2949], pp. 6-7. But the critical difference here is that unlike Dr. Pence, ***Dr. Harmanli is a medical doctor with extensive experience in teaching and working on medical journals***. Thus, unlike Dr. Pence, Dr. Harmanli has a reliable basis for opining about the general knowledge of treating physicians—no formal survey is needed. Dr. Harmanli's opinions about the knowledge of physicians are well-grounded in his background not only in clinical practice, but also in medical education and his work on journals.

Dr. Harmanli is board-certified in Obstetrics and Gynecology as well as Female Pelvic Medicine and Reconstructive Surgery. *See* Harmanli CV, p. 3 [Dkt. 6892-7, p. 4]. He has served in teaching positions for over two decades, teaching at Temple University School of Medicine, Tufts University School of Medicine; University of Massachusetts Medical School-Baystate, and Yale University School of Medicine, his current position. *Id*. at 2 [Dkt. 6892-7, p. 3]. Dr. Harmanli has been awarded recognition for his teaching on numerous occasions. *Id.* at 3-4 [Dkt. 6892-7, p. 4-5]. Dr. Harmanli is presently Chief of Urogynecology and Reconstructive Surgery and Professor of Obstetrics and Gynecology at the Yale School of Medicine. Harmanli Report, p. 1 [Dkt. 6892-2, p. 2]. Given this experience, Dr. Harmanli is well-versed in what is generally known by physicians and what is taught to them in their training.

In addition to this experience, Dr. Harmanli has also served on the editorial board of the Journal of Female Pelvic Medicine and Reconstructive Surgery, the official journal of American

Urogynecology Society. Harmanli Report, p. 2 [Dkt. 6892-2, p. 3]. He also served as chair of the Education Committee of Society of Gynecologic Surgeons and has created several teaching modules for American Professors of Gynecology and Obstetrics/Council on Resident Education in Obstetrics and Gynecology. *Id.* He was a member of the systematic review group of the Society of Gynecologic Surgeons and participated in the publication of systematic reviews including the reviews focusing on midurethral slings and transvaginal mesh procedures for pelvic organ prolapse. *Id.* at 3 [Dkt. 6892-2, p. 4]. From all of this experience, Dr. Harmanli has ample basis to opine about the general knowledge of surgeons treating stress urinary incontinence.

As this Court has held, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011)). This is precisely what Dr. Harmanli has reliably done, in reliance on his vast expertise, training, and experience. Plaintiffs' motion to exclude should be denied.

II. Dr. Harmanli's opinions regarding the Ethicon products' design are limited in scope and admissible.

Plaintiffs argue that Dr. Harmanli should not be permitted to offer "opinions on the design of the mesh products, including whether the devices are designed in reasonable manner." [Dkt. 6895, p. 9]. To be clear, Ethicon does not intend for Dr. Harmanli to offer any opinions about whether TVT or TVT-O are defective in design. However, he is well-qualified to testify about the risks and benefits of TVT and TVT-O as designed, as well as the risks and benefits of the alternative designs proposed by plaintiffs. To the extent these constitute "design opinions" they are admissible.

Plaintiffs' primary argument is that because Dr. Harmanli did not review Ethicon's internal design processes, such as the design failure modes effects analysis, then he cannot opine about design. [Dkt. 6895, pp. 10-11]. However, Dr. Harmanli's opinions are not about the compliance with Ethicon's internal design processes. Rather, Dr. Harmanli's opinions concern the risks and benefits of the completed product as designed, as well as alternatives.

Plaintiffs' reliance on the Court's opinion in *Winebarger v. Boston Scientific Corp.* is therefore misplaced. [Dkt. 6895, p. 10] (citing *Winebarger*, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015)). There, the Court excluded the opinions of the plaintiff's expert Dr. Shull *about the Boston Scientific design protocols* because he had not reviewed them.[1] Plaintiffs' attempt to expand that holding into one demanding review of internal design protocols as a prerequisite to opining about the design of a product should be rejected.

More on point is this Court's observation that a physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court, in particular, has made clear that a physician can draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products); *see also In re: Ethicon Inc.*, 2016 WL 4557036, at *3 (S.D.W. Va. Aug. 31, 2016) (permitting testimony from gynecologist about risks and benefits of the devices at issue based on her clinical experience and literature review); *In re C.R. Bard, Inc.*, 948

[1] *See Winebarger*, 2015 WL 1887222, at *14 ("Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way").

F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (ruling that an expert was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders").

Dr. Harmanli's opinions about the risks and benefits of TVT and TVT-O and alternative procedures are based on his extensive clinical experience and his literature review. *See* Harmanli Report, pp. 5, 6-13, 20-23. These provide a reliable basis for his opinions, and Plaintiffs' motion should be denied.

III. Dr. Harmanli's opinions regarding the lack of difference in clinical outcomes between the mechanically cut and laser cut TVT mesh are reliable and admissible.

Dr. Harmanli opines that there is no clinical difference between mechanically cut and laser cut mesh. He bases this opinion on two sources: his extensive history implanting the products, and the medical literature. Harmanli Report, p. 17 [Dkt. 6892-2, p. 18]. This opinion is reliable, and Plaintiffs' motion to exclude it presents fodder for cross-examination, not exclusion.

Plaintiffs argue that the opinion is unreliable because Dr. Harmanli acknowledged that there was a flaw in one of the studies cited, the Rusavy study, because the investigators changed the way they tensioned laser-cut TVT-O. Harmanli Dep. 163-164 [Dkt. 6892-4, pp. 14-15]. But Dr. Harmanli was clear that this does not undermine his ultimate opinion. *Id.* And for good reason. Plaintiffs are quick to point out that Ethicon did not advise physicians to tension laser-cut and mechanical-cut mesh differently, but that only proves the point. Dr. Harmanli (and other physicians too) does not tension laser-cut and mechanically-cut slings differently, and yet there was no difference in clinical outcome when laser-cut slings were introduced. If it were true that laser-cut slings had a different risk profile, then one would naturally expect that the outcomes

would change once those slings were introduced. Dr. Harmanli has been using these products for the entire time and has seen no such change.

Plaintiffs invoke this Court's prior ruling that "absence of evidence is not evidence of absence," but that principle is inapplicable here. *See Tyree*, 54 F. Supp. 3d at 584 (S.D.W. Va. 2014). This is not a situation where a physician has opined that a risk does not exist simply because he personally has not seen it in his patients. Rather, it is that a physician has not seen a change in the risk-profile of a single product during the course of his clinical use and his literature review over the years.

This Court has repeatedly found that experienced ob-gyns are qualified to offer opinions about mesh properties such as mechanical cutting vs. laser cutting. *See In re: Ethicon, Inc.*., 2018 WL 3545340, at *3 (S.D. W. Va. July 25, 2018) (finding Dr. Mueller qualified to testify regarding degradation, fraying, weight, density, porosity and cut (laser or mechanical) of the polypropylene mesh because of her "extensive experience treating women with pelvic floor disorders" and "review of the relevant medical literature"); *In re Ethicon Inc.*, 2018 WL 3611614, at *4 (S.D. W. Va. July 26, 2018 (same as to Dr. Shoemaker, a "board-certified gynecologist [who] has performed nearly 1,300 sling procedures for incontinence and over 700 procedures with either Gynecare PS, Prolift, Prolift+M, or Prosima"). Dr. Harmanli is well-qualified to offer opinions on mechanical vs. laser cutting of mesh by the same reasoning.

IV. Dr. Harmanli should be permitted to offer testimony about his own experience regarding the safety or efficacy of the mesh products.

Plaintiffs claim that "[t]his court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable." [Dkt. 6895, p. 14] (citing *In re: Ethicon, Inc.*, 2016 WL 4542054, at *4 (S.D. W. Va. Aug. 30, 2016)). But Dr.

Harmanli does not seek to offer precise statistics here. On this point, then, Plaintiffs' motion is moot.

To the extent Plaintiffs' motion seeks to preclude any other opinions about Dr. Harmanli's personal experience with pelvic mesh products,[2] the motion should be denied. As this Court has found:

> The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. The plaintiff's argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions.

Bellew v. Ethicon, Inc., No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014). In this same vein, this Court has recognized that a physician may testify that complication rates found in literature are verified by his personal experience. *See, e.g., Tyree v. Boston Scientific Corp*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert's opinion about safety and efficacy was reliable where opinion was based upon "minimal complications in his clinical practice" which was "'on par with the findings of [the] studies' he cites throughout his expert report").

Plaintiffs argue that Dr. Harmanli's opinions should be excluded because Dr. Harmanli "admits he does not know whether or not he is currently using the Ethicon laser cut mesh or the mechanically cut mesh." [Dkt. 6895, pp. 14-15]. However, this precisely proves Dr. Harmanli's point: that he cannot tell a difference in the way the products handle and perform and that his clinical outcomes did not change when laser-cut mesh was introduced. If Plaintiffs view this as a

[2] In this regard, Plaintiffs' motion is unclear. The heading of their memorandum on p. 14 argues that "Dr. Harmanli's opinions about his personal experience related to the safety and efficacy of the pelvic mesh products should be excluded . . ." but the body of that section states only that "Dr. Harmanli should be precluded from testifying about his perceived safety and efficacy rates . . . ." [Dkt. 6895, p. 14].

shortcoming in Dr. Harmanli's opinion (which it is not), that is grounds for cross-examination, not exclusion. *See Harris v. Norfolk Southern Ry. Co.*, 2013 WL 1136644, *3 (S.D. W. Va. Mar. 18, 2013) (on *Daubert* challenge, court "need not determine that the proffered expert testimony is irrefutable or certainly correct—as with all other admissible evidence, expert testimony is subject to testing by vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.") (internal quotations and citations omitted).

V. Dr. Harmanli's opinions about the degradation of polypropylene or its clinical significance are admissible.

Based on his extensive clinical experience and review of the literature, Dr. Harmanli opines that polypropylene does not degrade or that if it does, there is no clinical significance. *See* Harmanli Report, p. 22. This opinion is reliable and admissible.

First, Plaintiffs claim that Dr. Harmanli cannot offer this opinion because he does not have background or training in polymer chemistry. This argument is surprising, given that Plaintiffs' experts who are not polymer chemists have offered opinions about degradation. *See* Order, *Burkhart v. Ethicon, Inc. et al.*, No. 2:12-cv-01023, Dkt. 113, p. 4 (S.D. W. Va. Jan. 30, 2017) (permitting testimony by Dr. Rosenzweig about degradation and finding that "[t]o the extent Ethicon feels the basis of Dr. Rosenzweig's opinion is deficient, Ethicon may attack it on cross-examination").

Setting that aside, a urologists or gynecologist is qualified to testify about degradation. For instance, in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *45 (S.D. W. Va. May 19, 2016), the plaintiff argued that Dr. Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> As to qualification, Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's produces for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualified him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.

2016 WL 2939521, at *45 (other citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); *Huskey v. Ethicon*, 29 F. Supp. 3d 691, 706-07, 735 (S.D. W. Va. 2014) (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 550, 585 (S.D. W. Va. 2014) (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.). Like those experts, Dr. Harmanli offers the opinion that based on his clinical experience and review of the literature, he does not believe that polypropylene degrades.

Plaintiffs also criticize Dr. Harmanli's degradation opinion because he did not review the testimony of company witness Dr. Thomas Barbolt. However, as in the cases cited in the preceding paragraph, Dr. Harmanli's opinion is based on his clinical experience and literature review, not company documents. Further, Plaintiffs do not even explain why the testimony of

Dr. Barbolt is necessary for opining about degradation. And even if Dr. Harmanli had reviewed Dr. Barbolt's testimony, he would have found that they had reached the same conclusion.[3]

Alternatively, Dr. Harmanli opines that if polypropylene degrades, then it is not clinically significant. In their motion, Plaintiffs accuse Dr. Harmanli of cherry-picking studies, but in actuality, Dr. Harmanli's testimony is that a small number of outlier studies would not change his opinion in light of the vast body of long-term data on the products. *See* Harmanli Dep. at 178:23-182:3 ("even if it does [degrade], just like you are saying it would not change the clinical significance, because, again, we regard high quality, large prospective trials as the standard when we make decisions.") [Dkt. 6892-4, p. 19]. This is not "subjective belief or unsupported speculation," as Plaintiffs claim, but rather an expert weighing scientific evidence much in the manner he would do in his clinical practice.

In *Huskey*, this Court rejected a similar challenge to defense expert urogynecologist, Harry Johnson, M.D. *Huskey*, 29 F. Supp. 3d at 735. Noting that although "Dr. Johnson's opinion is not subject to testing and it is not supported by peer-reviewed literature *affirmatively* stating that degradation lacks clinical significance," Dr. Johnson's "clinical experience and his review of the scientific literature" set forth a sufficient basis for his opinion and "Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility." *Id.*

The same is true here. Dr. Harmanli has sufficient familiarity and experience with sling procedures, mesh slings generally, and the TVT and TVT-O in particular to provide reliable opinions on whether they degrade. His testimony is admissible.

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[3] *See* Ex. 1, Barbolt 1/8/2014 Dep. at 607:15-24 (Q. Dr. Barbolt, with respect to the 49 documents that you've identified in response to this issue of the materials not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes, did you find any information in any form that caused you concern that there was degradation from a preclinical perspective that caused you concern? MR. THORNBURGH: Objection. THE WITNESS: No.")

CONCLUSION

For these reasons, Plaintiffs' Motion to Exclude Certain Opinions of Dr. Oz Harmanli should be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this date I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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